DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1-6-06

1-9-06

[Docket No. 2005N–0507]

Agency Emergency Processing Under Office of Management and Budget Review; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA believes, and is preparing a guidance document explaining, that it is possible in certain circumstances for In Vitro Diagnostic (IVD) device studies to be conducted using leftover specimens obtained without informed consent while protecting the human subjects who are the source of such specimens. This notice solicits comments on the proposed collection of information associated with the guidance document entitled "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable."

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**]. FDA is requesting

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approval of this emergency processing by [*insert date 7 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. The Center for Devices and Radiological Health (CDRH) intends to issue a guidance document that addresses an immediate need of the research community. CDRH's guidance will identify the circumstances when the agency intends to exercise enforcement discretion regarding the informed consent requirements. These requirements normally apply to all FDA-regulated clinical studies, including studies using only leftover human specimens that are not individually identifiable. The agency intends to issue this guidance because the existing requirements are bringing a halt to a class of very valuable research that can produce new diagnostic tests, without appreciably adding protection for human subjects.

With respect to the following proposed collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions,

including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many IVD device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions (IDEs), under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (parts 50 and 56 (21 CFR parts 50 and 56)) apply

to all clinical investigations that are regulated by FDA (see §§ 50.1 and 56.101, and section 520(g)(3)(A) and (g)(3)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)(A) and (g)(3)(D))).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

FDA intends to notify the public, in a level 1 guidance document issued under the good guidances practices regulation (21 CFR 10.115), of the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs. In the guidance document, FDA recommends that sponsors of studies that meet the conditions maintain documentation of how these conditions were met and of the types of human subject protection procedures followed by the specimen provider to ensure that the subject cannot be identified.

Sponsors that wish to follow the recommendations of the guidance will substitute use of records to demonstrate conformance to this enforcement discretion policy in place of the more detailed and patient-specific records for obtaining and documenting informed consent. Most fundamentally, this means collecting and maintaining information about the protections that are in place to prevent the identification of the specimens, since making sure that the specimens are not identifiable is key to obtaining FDA's enforcement discretion.

FDA intends to exercise enforcement discretion when all the following are true:

- The investigation meets the IDE exemption criteria at § 812.2(c)(3);
- The study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded if not used in the study;
- The specimens provided to the investigator are accompanied by only minimal clinical information such as age, gender, and existing laboratory result;
- The specimens are not individually identifiable;
- The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information;
- The individuals caring for the patients are different from, and do not share information with, those conducting the investigation; and
- The study has been reviewed by an IRB in accordance with 21 CFR part 56.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
600	1	600	4	2,400

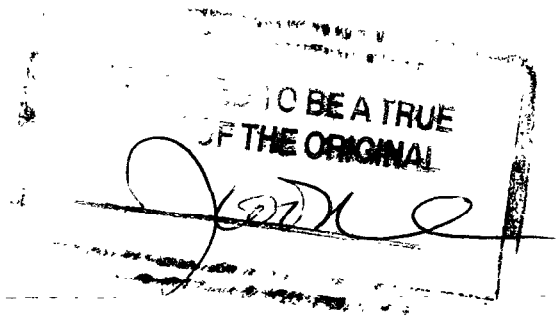
[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 600 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to

complete. This results in a total recordkeeping burden of 2,400 hours (600 x 4 = 2,400).

Dated: JAN 0 3 2006
January 3, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.



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